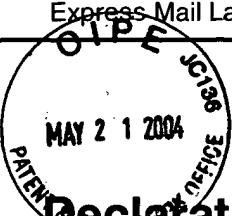


Docket No.

APP 1516

**Declaration and Power of Attorney For Patent Application**

This application claims the benefit under 35 U.S.C. § 119(e), of U.S. provisional patent application number 60/269,957 filed February 16, 2001.

**5 FIELD OF THE INVENTION**

This invention relates generally to wound dressings commonly associated with the vacuum induced healing of open wounds. More particularly, the present invention relates to a wound dressing, having a cell growth enhancing porous lattice, matrix, or scaffold, or a bioabsorbable layer as part of the dressing to enhance the wound healing.

**10 BACKGROUND OF THE INVENTION**

Vacuum induced healing of open wounds has recently been popularized by Kinetic Concepts, Inc. of San Antonio, Texas, by its commercially available V.A.C.® product line. The vacuum induced healing process has been described in commonly assigned U.S. patent 4,969,880 issued on November 13, 1990 to Zamierowski, as well as its continuations and 15 continuations in part, U.S. patent 5,100,396, issued on March 31 1992, U.S. patent 5,261,893, issued November 16, 1993, and U.S. patent 5,527,293, issued June 18, 1996, the disclosures of which are incorporated herein by this reference. Further improvements and modifications of the vacuum induced healing process are also described in U.S. patent 6,071,267, issued on June 6, 2000 to Zamierowski and U.S. patents 5,636,643 and 5,645,081 issued to Argenta et al. on June 20 10, 1997 and July 8, 1997 respectively, the disclosures of which are incorporated by reference as though fully set forth herein.

Substantial work has also been performed relating to the creation of bioabsorbable and includable, cell growth enhancing matrices, lattices, or scaffolds. Exemplary U.S. patents known

to applicant include Kemp et al. 5,256,418 issued October 26, 1993; Chatelier et al. 5,449,383 issued September 12, 1995; Bennett et al. 5,578,662 issued November 26, 1996; and two patents issued to Yasukawa et al. 5,629,186 issued May 13, 1997 and 5,780,281 issued July 14, 1998, both from a common parent application; the disclosures of which are incorporated by reference 5 herein.

As is well known to those of ordinary skill in the art, closure of surface wounds involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow 10 through damaged or broken vessels is stopped by capillary level occlusion; thereafter, cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the 15 wound not only receive diminished oxygen and nutrients, but also are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until the advent of vacuum induced therapy, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue 20 adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples may cause very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can eventually cause wound dehiscence and additional tissue loss.

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not repairable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with

5 staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been developed.

10 When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative gauge pressure, commercialized by Assignee or its parent under the designation "Vacuum Assisted Closure" (or "V.A.C.®") therapy, typically involves the mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this

15 manner, V.A.C.® therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While V.A.C.® therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because

20 the very nature of V.A.C.® therapy dictates an atmospherically sealed wound site, the therapy must often be performed to the exclusion of other beneficial, and therefore desirable, wound treatment modalities. One of these hitherto excluded modalities is the encouragement of cell growth by the provision of an *in situ* cell growth-enhancing matrix.

Additional difficulty remains in the frequent changing of the wound dressing. As the wound closes, binding of cellular tissue to the wound dressing may occur. Use of traditional V.A.C.® therapy necessitates regular changing of the dressing. Reckless dressing changes can result in some tissue damage at the wound site if cellular tissue has grown excessively into the 5 dressing.

Accordingly a primary object of the present invention is to provide an improved wound dressing for vacuum induced healing therapy, which overcomes the problems and limitations of the prior art.

A further object of the present invention is to provide a dressing that is also readily 10 adaptable to a variety of wound sizes and shapes and that requires no inordinate modification of known procedures for administration of V.A.C.® therapy.

Another object is to provide a pad that enables the concurrent application of vacuum induced healing and cell growth enhancement in the treating of a wound by providing a bioabsorbable, or includable, porous cell growth enhancing matrix substrate thereupon.

15 An additional object of the present invention is to allow for controlled application of growth factors or other healing factors, which could be embedded in the dressing or introduced into the dressing through a port or other connector fitting.

Still another object of the present invention is to provide a fully and/or partially 20 bioabsorbable wound dressing that minimizes disruption of the wound site during dressing changes.

A yet further object of the present invention is to provide such a dressing that is economical and disposable, but also safe for general patient use.